EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

INDIVIOR INC. *f/k/a* RECKITT BENCKISER PHARMACEUTICALS INC., and AQUESTIVE THERAPEUTICS, INC. *f/k/a* MONOSOL RX, LLC, Plaintiffs, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., Defendant.	Civil Action No.: 5:15-cv-00350-D

PLAINTIFFS' SECOND SET OF REQUESTS FOR PRODUCTION
PURSUANT TO RULE 34 (NOS 13-55)

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and all applicable Local Civil Rules of the United States District Court for the Eastern District of North Carolina, Plaintiffs Aquestive Therapeutics, Inc. ("Aquestive") and Indivior Inc. ("Indivior"), (collectively, "Plaintiffs"), request that Defendant BioDelivery Sciences International, Inc. ("Defendant" or "BDSI") answer separately and completely in writing within thirty (30) days of service hereof each of the requests set forth below and produce documents, at the offices of Steptoe and Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036. The following Requests are governed by the Definitions and Instructions set forth herein.

DEFINITIONS

The following Definitions apply throughout these Requests, regardless of whether upper- or lower-case letters are used:

1. The term "Aquestive" means Plaintiff Aquestive Therapeutics, Inc., formerly known as MonoSol Rx, LLC, and includes, without limitation, all parents, subsidiaries, affiliates, divisions, officers, directors, employees, partners, agents, attorneys, and representatives of Aquestive, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Aquestive.

2. The term "Indivior" means Plaintiff Indivior, Inc., formerly known as Reckitt Benckiser Pharmaceuticals Inc., and includes, without limitation, all parents, subsidiaries, affiliates, divisions, officers, directors, employees, partners, agents, attorneys, and representatives of Indivior, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Indivior.

3. The term "Plaintiffs" means Plaintiff Aquestive and/or Plaintiff Indivior, individually or collectively, and includes, without limitation, all parents, subsidiaries, affiliates, divisions, officers, directors, employees, partners, agents, attorneys, and representatives of either Aquestive or Indivior, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of either Aquestive or Indivior.

4. The terms "Defendant," "BDSI," "You" and "Your" mean Defendant BioDelivery Sciences International, Inc., and includes, without limitation, all parents, subsidiaries, affiliates, divisions and other entities owned or controlled by Defendant, if any; all officers, directors, employees, partners, agents, attorneys, representatives and owners (whether direct or indirect and legal, beneficial or otherwise) of entities owned or controlled by Defendant, if any, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Defendant or of any subsidiary, affiliate, division or entity owned or controlled by Defendant

5. The terms "'167 patent" and "patent-in-suit" mean U.S. Pat. No. 8,765,167.

6. The term "Asserted Claims" means claims 1, 4, 11-13, 16-18, 26, 30, 33, 36, 39, 42, 44-45, 48-49, 51-52, 55-56, 65-66, 69-70, 72-73, 76-77, 80-83, 86-87, 89, 92-93, 95-100, 103, 105-108, 110-111, 113-118, and 122-127 of the '167 patent, and any other claim of the '167 patent identified by Plaintiffs in a disclosure pursuant to E.D.N.C. Local Patent Rule 303.1(a).

7. The terms "this litigation" and "this matter" mean Plaintiffs' infringement suit against BDSI, Civil Action No. 5:15-cv-00350-D.

8. The term "Defendant's NDA" means BDSI's New Drug Application ("NDA") No. 205637, submitted under 21 U.S.C. § 505(b)(2), seeking approval to manufacture, market and sell BUNAVAIL throughout the United States, which was approved by the FDA on June 6, 2014, including any amendments and communications to or from the FDA relating to the NDA.

9. The terms "BUNAVAIL" and "Accused Product" means Defendant's BUNAVAIL® (buprenorphine and naloxone) buccal film products that are the subject of Defendant's NDA in the following doses: 2.1 mg buprenorphine/0.3 mg naloxone; 4.2 mg buprenorphine/0.7 mg naloxone; and 6.3 mg buprenorphine/1.0 mg naloxone.

10. The term "FDA" means the United States Food and Drug Administration.

11. The terms "Person" and "Persons" means any individual or entity, including, without limitation, a corporation, municipal corporation, partnership, joint venture, firm, trust, group association, governmental agency, commission, bureau or department and any division, department or other unit thereof.

12. The term "Entity" means any entity, including, without limitation, a corporation, municipal corporation, partnership, joint venture, firm, trust, group association, governmental agency, commission, bureau or department and any division, department or other unit thereof.

13. The term "Third Party" means and includes any Person or Entity other than

Defendant and Plaintiffs.

14. The term "communication" means the transmission of information (in the form of facts, ideas, inquiries or otherwise), whether orally or in writing (e.g., by fax, email, or any other means or medium), and includes without limitation all documents reflecting or concerning such communications.

15. The terms "thing" or "things" shall be defined as synonymous in meaning and equal in scope to the use of that term in Fed. R. Civ. P. 34(a) and includes any tangible object other than a document.

16. The term "document" is used in the broadest sense contemplated by Federal Rule of Civil Procedure 34 and includes the terms "writings and recordings," "photographs," "originals," and "duplicate" as defined in Federal Rule of Evidence 1001 and includes, without limitation, any and all tangible documents and things responsive to the document request as well as any other information regardless of the form in which the information has been stored, including electronically stored information within Your possession, custody, or control.

17. The terms "electronically stored information" or "ESI" mean any document, communication, code, architecture, internal software comments, or any other data or information present or stored on any computer, internal or external hard drive, jump drive, diskette, compact disc, database, server, or any other device or system capable of storing electronic files or information.

18. The terms "reflecting," "concerning," "regarding," "relating to," or "referring to" mean all documents or information that comprises, evidences, constitutes, describes, explicitly or implicitly refers to, was reviewed in conjunction with, or was generated as a result of the subject matter of the request, including but not limited to all documents that reflect, record, memorialize,

discuss, evaluate, consider, review, report, or relate to the subject matter of the request.

19. The terms "infringe" and "infringement" mean and refer to any and all types of infringement set forth in 35 U.S.C. § 271, including direct infringement, contributory infringement, inducement of infringement, literal infringement, and/or infringement under the doctrine of equivalents.

20. The term "employee" means any person currently or formerly serving, acting, or existing as an employee or agent, including employees, agents, attorneys, partners, associates, financial advisors, consultants, investigators, and any other person acting on behalf of the person referred to, pursuant to the authority of the person referred to, or subject to the control of the person referred to.

21. The term "identify" when used with respect to an activity, an occasion or a transaction means and refers to providing: the date of the act; the identity of the persons who participated in the act; the identity of each person who witnessed such act; and a general description of the act.

22. The term "identify" when used with respect to persons means to state the person's name, title (or job description), present or last known employer or business association, and present or last known address.

23. The term "identify" when used with respect to documents means to provide the following information irrespective of whether the document is deemed privileged or subject to any claim of privilege:

a) the title or other means of identification of the document;

b) the date of the document;

c) the author of the document;

d) the recipient or recipients of the document;

e) the subject matter of the document;

f) the present location of any and all copies of the document in the possession, custody or control of Defendants; and

g) the names and current addresses of any and all persons who have possession, custody, or control of the document or copies thereof.

24. "And" and "or" shall be construed conjunctively and disjunctively so as to acquire the broadest possible meaning.

25. The terms "any," "all," or "each" shall be construed as "any, all and each."

26. The singular and masculine form of a noun or pronoun shall embrace, and shall be read and applied as, the plural or the feminine or neuter, as the particular context makes appropriate or permits to obtain the broadest possible meaning.

27. The use of the singular form of any word shall include the plural and vice versa.

INSTRUCTIONS

1. These discovery requests extend to all documents in the possession, custody, or control of Defendant, and/or in the possession, custody, or control of any and all of Defendant's Entities and Affiliates, and/or in the possession, custody, or control of any and all other Entities whom Defendant and/or its Entities or Affiliates direct or control, or otherwise available to Defendant.

2. In the event more than one copy of a document exists, Defendant shall produce the original and each non-identical copy of each document or other tangible thing requested herein.

3. Each discovery request shall be fully responded to unless it is in good faith objected to, in which event the reasons for your objection shall be stated in detail. If an objection pertains

only to a portion of a discovery request, or a word phrase, or clause contained within it, you are required to state your objection to that portion only and to respond to the remainder of the discovery request, using your best efforts to do so.

4. To the extent Defendant alleges that the meaning of any term in these discovery requests is unclear, Defendant is to assume a reasonable meaning, state that assumed reasonable meaning and respond to the request on the basis of that assumed meaning.

5. All requested documents produced by Defendant shall be organized either to correspond to the categories in these discovery requests, or as they are kept in the ordinary course of business. In either case, all documents produced shall:

(a) be produced with all associated file labels, file headings, and file folders together with the responsive documents from each file, and each file shall be identified as to its owner or custodian; for any document originally stored in electronic media, the file name, path, and directory information for each such documents shall also be provided;

(b) if produced in hard copy, all pages now stapled or fastened together shall be produced stapled or fastened together, and shall include all attachments currently or previously appended to each document, regardless of whether such attachments themselves are responsive to these requests;

(c) if produced electronically, all attachments currently or previously appended to the electronic file shall be produced, regardless of whether such attachments themselves are responsive to these requests;

(d) all documents that cannot be legibly copied shall be produced in original form.

6. If any document identified in response to any of these discovery requests was, but is no longer in the possession, custody, or subject to the control of Defendant, or is no longer in

existence, state whether it:

(e) is missing or lost;

(f) has been destroyed;

(g) has been transferred, voluntarily or involuntarily, to others and state the identity of those persons to whom it has been transferred;

(h) has been otherwise disposed of, and in each instance, explain the circumstances surrounding such disposition, state the date or approximate date thereof, and the identity of the persons with knowledge of such circumstances; or

(i) identify the writings that are missing, lost, destroyed, transferred, or otherwise disposed of, by author, date, subject matter, addressee, and the number of pages.

7. With respect to any claim of a privilege by Defendant regarding any information, document, or communication sought by any of Plaintiffs' discovery requests, and consistent with Federal Rules of Civil Procedure 26(b)(5), Defendant is requested to individually identify each such communication, information, or document withheld on grounds of an alleged privilege, and specifically set forth:

(a) the nature of the privilege claimed, as well as the grounds for withholding the communication, document, or information, including the specific facts upon which you rely upon to establish the privilege;

(b) the nature of the communication, document, or information, whether written, oral or both;

(c) the author(s) or speaker(s), as well as their titles and positions;

(d) all addressee(s), as well as their titles and positions;

(e) all persons who received copies, as well as their titles and positions;

(f) the date of the communication, document, or information;

(g) the subject matter of the communication, document, or information; and

(h) the specific document requests to which the communication, document, or information is responsive.

8. Each discovery request shall be construed independently and not with reference to any other discovery request for the purpose of limitation.

9. None of the discovery requests shall be construed as an admission relating to the existence of any evidence, to the relevance or admissibility of any evidence, or to the truth or accuracy of any statement or characterization in the discovery request.

10. Pursuant to Rule 26(e) of the Federal Rules of Civil Procedure, these requests are deemed to be continuing in nature to the full extent required by the Federal Rules of Civil Procedure. If further responsive documents come into the possession or to the attention of Defendant or its attorneys at any time during the course of this litigation, such documents must be produced as required by the Federal Rules of Civil Procedure.:

REQUESTS FOR PRODUCTION OF DOCUMENTS

REQUEST FOR PRODUCTION NO. 13:

All documents and things relating to the research, development, and testing of any pharmaceutical film product regardless of what active ingredient is involved (i.e., products in which the active ingredient is carried within a film formulation), performed by, on behalf of, or at the direction of Defendant including all documents relating to: (i) manufacturing processes attempted; (ii) evaluations, measurements, or tests relating to the distribution of active ingredients in an individual dosage unit; (iii) the identity, amounts, and proportions of excipients tried; (iv) the identity, amount, and proportion of active ingredients tried; (v) attempts to vary a drying process, including attempts to vary at least one controlled drying parameter, including but not limited to air current temperature, air current velocity, air current humidity, drying time, direction

or location of a heat source or air current, type of radiation, or intensity of radiation; (vi) attempts to vary a drying process to avoid a rippling effect; and (vii) any patents or published literature relied on during the course of such research, development, and testing.

REQUEST FOR PRODUCTION NO. 14:

All documents and things relating to any and all sublingual films formulated with buprenorphine or naloxone, ever designed, studied, researched, analyzed, developed, made, used, manufactured, sold, promoted, marketed, offered for sale, distributed, or demonstrated by or on behalf of Defendant, including but not limited to Defendant's BUNAVAIL Products, including without limitation all documents and things concerning:

(a) conception, research, comparisons, tests, evaluations, studies, analyses, design or development;

(b) manufacture or production;

(c) distribution, use, marketing, advertising, demonstration, offers for sale, or sales;

(d) all business and marketing plans, budget reviews, business group plans, market share analyses, sales group plans, market surveys, market studies or evaluations, sales results, profit results, competitive analyses, profitability analyses, sales projections, and advertising plans;

(e) all promotional literature, advertisements, sales and marketing information, brochures, flyers, handouts, specification sheets, or the like;

(f) all purchase or sale contracts, draft contracts, proposed contracts, purchase orders, or offers for sale; and

(g) all budgeted and actual costs for research and development, manufacturing, marketing, advertising, administration, distribution, quality control, warranty, goods, inventory, or sales.

REQUEST FOR PRODUCTION NO. 15:

All correspondence, agreements, and/or contracts between or among Defendant and any

and all third parties with regard to any aspect of the product that ultimately was approved as the BUNAVAIL product, including research and development, manufacture or production, ingredient sourcing, and/or marketing and promotion.

REQUEST FOR PRODUCTION NO. 16:

All documents and things discussing or otherwise referring to the impact of a drying process on the distribution of an active ingredient in a pharmaceutical film product, including but not limited to the impact of varying the type of heat source(s), the location of the heat source(s), or at least one controlled drying parameter (e.g., air current temperature, air current velocity, air current humidity, drying time, type of radiation, or intensity of radiation) on the uniform distribution of an active ingredient in a pharmaceutical film product.

REQUEST FOR PRODUCTION NO. 17:

All documents and things discussing or otherwise referring to the methods of avoiding a rippling effect during a drying process on the uniform distribution of an active ingredient in a pharmaceutical film product.

REQUEST FOR PRODUCTION NO. 18:

All documents and things discussing or otherwise referring to drying processes used in the manufacture of a pharmaceutical film, including but not limited to how those drying processes impact the distribution of the active ingredient in the film.

REQUEST FOR PRODUCTION NO. 19:

All documents and things concerning any patent literature, non-patent literature (including but not limited to any publications, articles, or abstracts), or oral or written presentations authored, prepared, or made by Defendant, or at the instruction of or on behalf of the Defendant, concerning pharmaceutical film technology, buprenorphine, naloxone, or a drying process of a pharmaceutical

film product.

REQUEST FOR PRODUCTION NO. 20:

All documents and things concerning any patents or patent applications, whether in the United States or in foreign countries, that Defendant has filed or that have been assigned to Defendant concerning pharmaceutical films, including any communications to or from the United States Patent and Trademark Office and/or foreign patent offices concerning any such patents or patent applications.

REQUEST FOR PRODUCTION NO. 21:

All documents concerning any analysis comparing or contrasting any of the claims of the patent-in-suit with any formulation or product of Defendant or of any other person or entity, including Defendant's BUNAVAIL Products.

REQUEST FOR PRODUCTION NO. 22:

All documents relating to or referring to any materials that Defendant contend are prior art to the patent-in-suit.

REQUEST FOR PRODUCTION NO. 23:

All validity or patentability prior art searches or investigation reports relied upon, reviewed, generated, performed, commissioned, ordered, requested, received, contracted, or purchased by Defendant with regard to the patent-in-suit.

REQUEST FOR PRODUCTION NO. 24:

All documents relating or referring to any attempts to replicate, reverse engineer, or deformulate examples of products or processes disclosed in any of the patent-in-suit or any related patents.

REQUEST FOR PRODUCTION NO. 25:

All documents and things that relate to secondary considerations pertaining to the patentability of the claims of the patents-in-suit under 35 U.S.C. § 103, including all such secondary consideration information that Defendant contends militates in favor of finding any of such claims obvious or which tends to undermine or contradict such contentions.

REQUEST FOR PRODUCTION NO. 26:

All documents and things referring or relating to what Defendant contend to be the level of a person of ordinary skill in the area of the patents-in-suit, including any and all information relating to the state of the art in pharmaceutical film technology as of about 2001, 2002, and 2006, including all such information that Defendant contends support those positions or that tends to undermine or contradict such contentions.

REQUEST FOR PRODUCTION NO. 27:

All documents that refer to, relate to, support, demonstrate, or evidence the obviousness or non-obviousness of any inventions claimed in the patent-in-suit, including all such information that Defendant contends supports their positions on obviousness.

REQUEST FOR PRODUCTION NO. 28:

All documents that Defendant contends support or demonstrate any motivation or lack thereof to combine prior art teachings to yield the inventions claimed in the patent-in-suit.

REQUEST FOR PRODUCTION NO. 29:

All documents and things relating to Defendant's assertions that one or more claims of the patent-in-suit are invalid, including all such information that Defendant contends supports those positions or which tends to undermine or contradict such contentions.

REQUEST FOR PRODUCTION NO. 30:

All documents and things relating to Defendant's assertions that one or more claims of the patent-in-suit are unenforceable, including all such information that Defendant contends supports those positions or which tends to undermine or contradict such contentions.

REQUEST FOR PRODUCTION NO. 31:

All legal opinions relating to the interpretation, construction, scope, and meaning of the claims in the patent-in-suit.

REQUEST FOR PRODUCTION NO. 32:

All legal opinions relating to the validity, enforceability, or existence of infringement of the patent-in-suit.

REQUEST FOR PRODUCTION NO. 33:

All documents and things relating to Defendant's decision(s) to develop and market a sublingual film containing buprenorphine and/or naloxone, including but not limited to consideration of: (i) medical patient or treatment needs; (ii) advantages of a film formulation with a uniform distribution of an active ingredient in or among individual doses, such as an active ingredient not varying by more than 10% between individual doses; (iii) market and competitor analysis; (iv) profit, revenue, and market share expectations.

REQUEST FOR PRODUCTION NO. 34:

All documents relating to Defendant's decision to file an NDA for Defendant's BUNAVAIL Products.

REQUEST FOR PRODUCTION NO. 35:

All documents reflecting internal communications relating to Defendant's BUNAVAIL Products, the patents-in-suit, Defendant's NDA, or this litigation.

REQUEST FOR PRODUCTION NO. 36:

All documents reflecting communications between Defendant and any third party relating to Defendant's BUNAVAIL products, the patents-in-suit, Defendant's NDA, or this litigation.

REQUEST FOR PRODUCTION NO. 37:

All documents concerning pricing strategies, price evaluations, or considerations of what price to charge for any and all of Defendant's BUNAVAIL Products.

REQUEST FOR PRODUCTION NO. 38:

All documents referring to the potential or actual commercial demand for a pharmaceutical film containing buprenorphine as the sole active ingredient.

REQUEST FOR PRODUCTION NO. 39:

All documents and things concerning studies, valuations, evaluations, or reports conducted on behalf of, or at the direction of, Defendant by any other third party relating to any and all of Defendant's BUNAVAIL Products, this litigation, the patent-in-suit, or any patent or patent application relating to formulations of buprenorphine and/or naloxone.

REQUEST FOR PRODUCTION NO. 40:

All documents and things relating to any communications between Defendant and any physicians, patients, or any other person or entity concerning Defendant's BUNAVAIL Product or any other buprenorphine or naloxone composition.

REQUEST FOR PRODUCTION NO. 41:

All organizational charts and other documents showing the past and present organizational and operational structure of Defendant since 2012, including all divisions, direct and indirect parents and subsidiaries, entities owned or controlled by Defendant, affiliates, predecessors, or successors in interest, and the identities of any officers, employees, and representatives, such as,

without limitation, department officer/employee organizational charts.

REQUEST FOR PRODUCTION NO. 42:

All documents and things relating to the communication by Defendant to any third party of any information generated, produced, or conveyed by Plaintiffs, including any confidential information regarding film technology.

REQUEST FOR PRODUCTION NO. 43:

All documents and things relating to any communication with any current or former employee or consultant of Plaintiffs.

REQUEST FOR PRODUCTION NO. 44:

All documents and things that relate to correspondence and/or communications between Defendant and any person regarding any of the patents-in-suit or any other patent owned by or assigned to Plaintiffs.

REQUEST FOR PRODUCTION NO. 45:

All documents and things relating to communications between Defendant and any person regarding sublingual film technology described in patent or non-patent literature.

REQUEST FOR PRODUCTION NO. 46:

All documents and things relating to communications between Defendant and any person regarding any drying process for buccal, sublingual, or any other oral pharmaceutical film technology described in patent or non-patent literature.

REQUEST FOR PRODUCTION NO. 47:

All documents and things relating to communications between Defendant and any person regarding any buccal, sublingual, or any other oral pharmaceutical containing buprenorphine and/or naloxone, in any dosage, including but not limited to Defendant's BUNAVAIL Products.

REQUEST FOR PRODUCTION NO. 48:

All documents and things that relate to Defendant's consideration, decision, or effort to identify parties which could assist in the formulation and manufacture of Defendant's BUNAVAIL Products, including any work done to develop the formulation, the amounts and proportions of all ingredients and materials used in the formulation, and all associated processing methods and manufacturing steps, including associated drying processes.

REQUEST FOR PRODUCTION NO. 49:

All documents, including agreements and/or communications between Defendant and any third party, related to the development, manufacture, testing, marketing, or sales of Defendant's BUNAVAIL Products.

REQUEST FOR PRODUCTION NO. 50:

All documents relied upon by, considered by, or provided in connection with this litigation, for each expert who you expect to give testimony at trial, to the extent not precluded by Rule 26, Fed.R.Civ.P., as amended.

REQUEST FOR PRODUCTION NO. 51:

All work papers and all documents created in connection with this litigation by each expert who you expect to give testimony at trial, including correspondence sent from or to Defendant or its counsel, to the extent not precluded by Rule 26, Fed.R.Civ.P., as amended.

REQUEST FOR PRODUCTION NO. 52:

For each expert preparing a report, declaration, or affidavit on behalf of Defendant, all documents concerning the data or other information considered by the expert in forming his/her opinions.

REQUEST FOR PRODUCTION NO. 53:

All press releases, transcripts, or reports of Defendant's public statements concerning this litigation or any product, composition, or process alleged to infringe the patents-in-suit or any related patents.

REQUEST FOR PRODUCTION NO. 54:

All documents and things identified in Defendant's responses to interrogatories served in this litigation.

REQUEST FOR PRODUCTION NO. 55:

All documents and things that Defendant plans to use, rely upon, or intends to offer into evidence at any trial or hearing in this litigation.

Date: November 3, 2021.

Respectfully submitted,

/s/ E. Bradley Evans

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CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2021, I have served the foregoing documents on all counsel of record.

/s/ E. Bradley Evans

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